UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,206	01/02/2002	Vishwanath R. Lingappa	UCSF.002.01US	1150

31272 7590 05/17/2005

RAE-VENTER LAW GROUP, P.C.
P.O. BOX 1898
MONTEREY, CA 93942-1898

EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,206	LINGAPPA ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14, 51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed March 4, 2005 in response to the Office Action of August 2, 2004 is acknowledged and has been entered. Claims 12-14, 51-54 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The office acknowledges the amendments to the specification.

Claim Rejections - 35 USC § 112

The rejection of claims 12-14, 51-53 and newly added claim 54 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** essentially for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. Applicants urges that the specification supports the existence of at least two tertiary structures of the amino acid sequence set out in SEQ ID NO:6. The supposed existence of two tertiary structures is based on an immunoprecipitation experiment (Figure 14 in the specification) in which applicants find that HP68 associates with Gag when Gag is expressed in Cos-1 cells. Applicants point to this experiment as indicating that there are two different conformers (i.e. two different conformational structures of the same protein) where one conformation structure associates with

Gag and another conformational structure associates with RNase L inhibitor. From the experimental design this is not the only interpretation that can explain the results. The results can also be interpreted as follows: (1) the HP68 may have a higher affinity for Gag and therefore the cellular pool of HP68 will associated with Gag when Gag is present in the cell and thereby no longer associate with RNase L, or (2) alternatively the presence of a plasmid or Gag in the cell may stimulate the cell to produce more of the RNase L inhibitor which then binds to RNase L displacing HP68 form the RNase L.

Applicants additionally make the argument that the scenarios posed by the Examiner are inept because the data generated by the Applicants uses a cell free system, therefore no cellular pool of HP68 is present. Applicants' argument on this point is not convincing. The sole thrust to convince the Office that there are two different conformational structures of the same protein is based on the experiments set out in Figure 14. The experiments of Figure 14 utilize a cell transfection assay using Cos-1 cells (Cos-1 cells are eukaryotic cells and therefore by definition the experiments are not based on a cell free system). Applicants' arguments have been fully considered but are not convincing.

The term "conformer" renders the claims indefinite because the ordinary artisan would not know what is meant by this term. The specification has not provided a way to distinguish between the "conformers" (i.e. two different conformational structures of the same protein). Does "conformer" refer to the immature capsid in association with HP68 or does conformer refer to a mutant of HP68. The phrase "conformer" renders the claims indefinite because the specification does not provide a standard of measuring the degree intended by the term, thereby

rendering the scope of the claim(s) unascertainable. The rejection is maintained for reasons of record.

The rejection of claims 12-14, 51-53 and newly added claim 54 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is maintained** for reason of record.

Applicant's arguments have been fully considered but fail to persuade. Applicant's argument is that the rejected "claims are original claims in the application as filed, and therefore, by definition applicants were in possession of the claimed subject matter at the time the application was filed." Applicants' arguments are not convincing, applicant is advised to review the written description guidelines that became effective in January 5, 2001. (64 FR 71427, Dec 21, 1999 and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000). The guidelines require that "[t]he analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicants has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed and should include a determination of the field of the invention and the level of skill and knowledge in the art." The prior rejection indicated that the knowledge of knockout mice and the production of such mice is not a trivial matter and that the general description would not be sufficient to describe the particular mouse needed for the invention.

Applicants have not addressed the substantive issues raised in the prior rejection. There is insufficient written description for the claimed antibodies that required the existence of a knockout mouse. The knockout mouse is not described in the specification and there are no antibodies disclosed that were made using such a knock out mouse. The claims encompass a genus of compounds (monoclonal antibodies) defined only by their function "binding to a conformer" without disclosing the structural differences between the "conformers." There is no objective evidence in the specification as filed that would indicate the binding affinity differences in the HP68 molecule is due to conformational constraints of the HP68 molecule itself. The difference in the binding affinity of the target molecules could account for the different association of Hp68.

The specification has not provided a written description of how to determine the difference in structure between the "the conformation of the chaperone protein involved in the assembly of immature viral particles and the conformation of the chaperone that do not bind Gag." The amended claims remain rejected because the specification does not provide sufficient written description for the knockout mouse or the antibodies.

The rejection of claims 12-14, 51-53 and newly added claim 54 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained** for reasons of record.

Applicants arguments are that they have avoided this rejection by amending the claims to set out specific steps used to produce the knock out mouse. The amendment and the arguments

fail to address the unpredictability in the art of making knockout animals. The rejection is maintained for reason of record. The specification has not provided a means of distinguishing the difference in structure between the "the conformation of the chaperone protein involved in the assembly of immature viral particles and the conformation of the chaperone that do not bind Gag." Applicants specification hypothesizes that there are different structural conformation of the same protein. The hypothesis is based on the different binding affinities of the HP68 and the different targets. The different binding affinities between the different target could just as well be based on the structure of the target and have nothing to do with the structure of the HP68. Yet the claims are broadly drawn to include methods of distinguishing different structures of HP68 when it has not been established that HP68 even has different structures. Because the creation of a knock out mouse is unpredictable, the creation of antibodies using this animal is also unpredictable. The amended claims remain rejected.

Claim Rejections - 35 USC § 102

The rejection of claim 13 under 35 U.S.C. 102(b) as being anticipated by Willison et. al (Cell, 1989) as evidenced by applicants specification page 45 lines 25-27 indicating that the 23c antibody was used for the isolation of the WG68 conformer **is maintained** for reasons of record. Applicants have amended the claim so that it now reads on a product by process. For this office action, the product by process claim is interpreted as "a composition of matter." Product by process claims are not limited to the manipulations of the recited steps in the prior claims from which the instant claim is now dependent on, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

The cited art discloses the monoclonal antibody that was used in the process of identifying a chaperone protein WG68 found in wheat germ extract. The 23c antibody recognizes a number of eukaryotic proteins. The rejection is maintained.

Claim Rejections - 35 USC § 103

The rejection of claims 13 and 14 under 35 U.S.C. 103(a) as being obvious over Willison et. al (Cell, 1989) is maintained for reasons of record. as evidenced by applicants specification page 45 lines 25-27 indicating that the 23c antibody was used for the isolation of the WG68 conformer **is maintained** for reasons of record. Applicants have amended the claim so that it now reads on a product by process. For this office action, the product by process claim is interpreted as "a composition of matter." Product by process claims are not limited to the manipulations of the recited steps in the prior claims from which the instant claim is now dependent on, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

The cited art teaches the monoclonal antibody that was used in the process of identifying a chaperone protein found in wheat germ extract. The 23c antibody recognizes a number of eukaryotic proteins. Once an antibody is known and isolated, the binding fragments of the antibody are obvious. The rejection is maintained.

Claim Rejections - 35 USC § 112

The rejection of claims 13 and 14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** because after another review of the specification by the examiner it appears that applicants had purchased the 23c antibody from Stressgen in Vancouver Canada. Therefore, the antibody appears to be readily available because it could be purchased.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 5/12/05